GENTEAL SEVERE- hypromellose gel
Novartis Pharmaceuticals Corporation

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredient	***Purpose***
Hypromellose 0.3%.	Lubricant

Uses

- temporarily relieves discomfort due to minor irritations of the eye or to exposure to wind or sun
- as a protectant against further irritation or to relieve dryness of the eye

Warnings

For external use only

Do not use

- if gel changes color or becomes cloudy
- if you are sensitive to any ingredient in this product

When using this product

- do not touch tip of container to any surface
- replace cap after using

Stop use and ask a doctor if you experience any of the following:

- eye pain
- changes in vision
- continued redness or irritation of the eye
- condition worsens or persists for more than 72 hours

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- put 1 or 2 drops in the affected eye(s) as needed

Other information

- store between 15º - 25ºC (59º - 77ºF)

Inactive ingredients

carbopol 980, phosphonic acid, purified water, sodium hydroxide, sodium perborate, and sorbitol

Questions?

In the U.S., call toll-free
1-800-757-9195
(Mon-Fri 9AM-5PM CST)
alcon.medinfo@alcon.com

PRINCIPAL DISPLAY PANEL

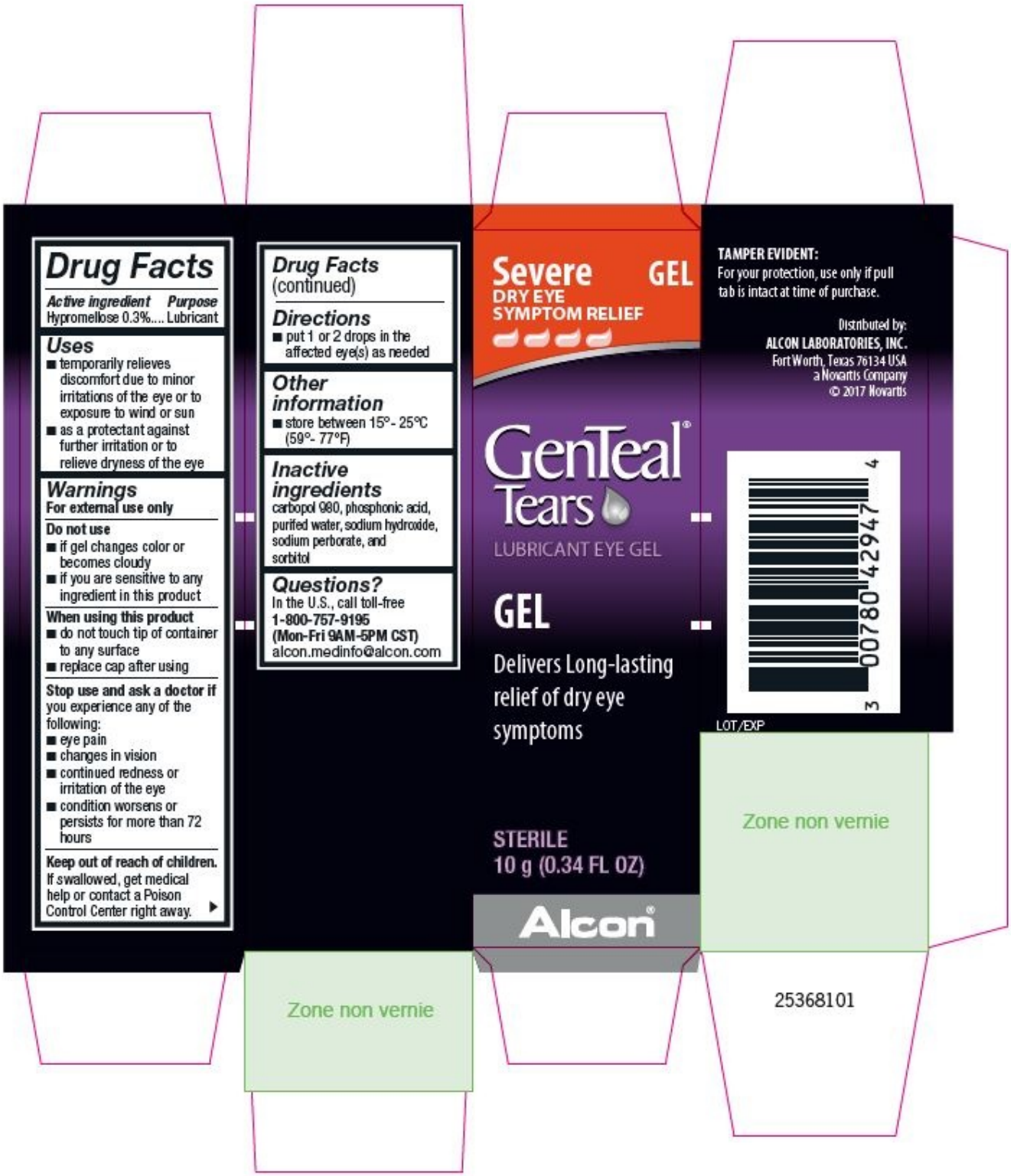
Severe DRY EYE SYMPTOM RELIEF
GEL

GenTeal® Tears
LUBRICANT EYE GEL

GEL
Delivers Long-lasting relief of dry eye symptoms

STERILE
10 g (0.34 FL OZ)

Alcon®



NDC 0078-0429-47

Severe
DRY EYE SYMPTOM RELIEF
GEL

GenTeal® Tears
LUBRICANT EYE GEL

GEL
Delivers Long-lasting relief of dry eye symptoms

New Design

STERILE
10 g (0.34 FL OZ)

Alcon®

Distributed by:
ALCON LABORATORIES, INC.
6201 South Freeway
Fort Worth, Texas 76134 USA
a Novartis Company
Country of Origin: Switzerland

GENTEAL SEVERE

hypromellose gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0078-0429
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Hypromellose 2910 (4000 Mpa.S) (UNII: RN3152OP35) (Hypromellose 2910 (4000 Mpa.S) - UNII:RN3152OP35)	Hypromellose 2910 (4000 Mpa.S)	.003 g in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
Sodium Perborate (UNII: Y52BK1W96C)	
Phosphonic Acid (UNII: 35V6A8JW8E)	
Water (UNII: 059QF0KO0R)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Sorbitol (UNII: 506T60A25R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0078-0429-97	1 in 1 CARTON	09/14/2009	02/28/2015
1		3.5 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0078-0429-47	1 in 1 CARTON	09/14/2009	08/31/2021
2		10 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:0078-0429-57	2 in 1 CARTON	09/14/2009	08/31/2019
3		10 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	09/14/2009	08/31/2021

Labeler - Novartis Pharmaceuticals Corporation (002147023)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn AG		482198285	manufacture(0078-0429) , label(0078-0429) , pack(0078-0429)

Establishment

Name	Address	ID/FEI	Business Operations
Excelvision		274234566	manufacture(0078-0429) , label(0078-0429) , pack(0078-0429)

Establishment

Name	Address	ID/FEI	Business Operations
SERVIPACK		571772875	label(0078-0429) , pack(0078-0429)

Revised: 1/2020 Novartis Pharmaceuticals Corporation